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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/767,346	01/23/2001	Pamela L. Plouhar	26502-67310	3293

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EXAMINER
PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 12/18/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/767,346	Applicant(s) PLOUHAR ET AL.	
	Examiner Paul B. Prebilic	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *49-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *49-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Claim Objections

Claim 55 is objected to because of the following informalities: On line 5 of claim 55, there should be a comma between "site" and "said" in order to be less grammatically awkward. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,782,915) in view of Whitson et al (US 5,968,096). Stone discloses removing up to the entire joint down to the cancellous bleeding bone, but fails to disclose the submucosa of 1 to 12 mm thick as claimed; see the entire document, especially column 6, lines 6-16. Whitson, however, teaches that an 8-layer submucosa graft has been known to the art and that it can be used in any grafting procedure; see the whole document, especially Example 2. It is asserted that the 8-layer submucosa graft would be approximately or about 1 mm in thickness. Hence, it is the Examiner's position that it would have been obvious to use the submucosa graft of Whitson in the method of Stone for the same reasons that Whitson desires this tissue over other prior art tissue (i.e. for the enhanced mechanical and remodeling properties).

With regard to claims 50-52, if the entire joint is removed, then all the types of cartilage would inherently removed along therewith. For this reason, the claims are met by the method of Stone in this regard.

With regard to claim 54, the fibrin clot is the barrier layer as claimed.

Claims 49-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,881,733) in view of Badylak et al (US 5,281,422). Stone teaches using other tissues to repair a joint as claimed where such other tissues have thicknesses of 1 to 2 cm (10 to 20 mm); see whole document, especially the abstract and column 2, lines 10-11. Stone does not disclose the use of submucosa as claimed. However, Badylak et al teaches that it was known to make multiplayer submucosa grafts to repair bones. Hence, it is the Examiner's position that it would have been obvious to use submucosa to repair the joint of Stone and to make it 10 mm in thickness for the same reasons that Badylak desires using the same for bone repair.

Claim 55 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,782,915) in view of Bolesky (WO 95/06439) or Braun (US 3,562,820). Stone discloses removing up to the entire joint down to the cancellous bleeding bone, but fails to disclose using multiple layered submucosa grafts. Instead Stone uses non-human cartilage; see the entire document, especially column 6, lines 6-16. However, both Bolesky and Braun teach the advantage of using multiple layered submucosa as tissue grafts to replace or repair tissues in the body; see Bolesky, especially the abstract, page 1, lines 9-17 and pages 7 to 11, and see Braun, especially the abstract, column 2, lines 18-71. Hence, it is the Examiner's position that it would have been obvious to use the

mulilayered tissue grafts of Bolesky or Braun in the Stone method in order to improve the antigenic properties of the implant and for the same reasons that the secondary patents use the same.

Response to Arguments

Applicant's arguments filed September 27, 2002 have been fully considered but they are not persuasive. Applicant argues that the effective filing date of claims 49-54 is April 5, 1996. However, upon review of the US 5,788,625, it was determined that the effective filing date of claims 49-54 is April 4, 1997 because at least the range limitation of about 1 to about 12 mm was added on that date. Applicant is directed to note that the 08/628,773 disclosure had a narrower range of about 4 to 8 mm thickness with a narrower range of layers; see US 5,788,625 on column 5, lines 12-60 and compare to parent application 08/913,771 as US 6,176,880 on column 4, line 20 to column 5, line 36. Note that the '625 patent basically equates 4 to 8 mm thick tissue to 50 to 200 layers of replacement tissue; see column 5, lines 31-35. For this reason, the rejections have been maintained.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
AU 3738